

REMARKS

Claims 36-44, 46, 47, 49, 51-55, 57-60, and 69-76 remain pending in this application. In this Response, claims 53 and 57 have been amended and claim 56 has been cancelled. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Obviousness Rejections

Claims 53-55 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,073,373 to O’Leary et al. (“O’Leary”) in view of U.S. Patent No. 4,573,448 to Kambin (“Kambin”). Claim 52 was rejected under 35 U.S.C. §103(a) as being unpatentable over O’Leary in view of Kambin and further in view of U.S. Patent No. 4,828,563 to Muller-Lierheim (“Muller-Lierheim”) and U.S. Patent No. 4,210,580 to Amrani (“Amrani”). Claim 56 was rejected under 35 U.S.C. §103(a) as being unpatentable over O’Leary in view of Kambin and further in view of U.S. Patent No. 4,936,848 to Bagby (“Bagby”). For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by O’Leary, Kambin, Muller-Lierheim, and Amrani, either alone or in the combinations set forth in the Office Action.

As an initial matter, claim 56 has been cancelled to expedite prosecution and without prejudice to pursue in a divisional or continuation application. Accordingly, this cancellation should not be construed as any concession or admission concerning the rejection.

O’Leary discloses a flowable demineralized bone powder composition for use in surgical bone repair (col. 1, lines 27-29). The bone powder can be obtained from cortical, cancellous and/or corticocancellous allogenic or xenogenic bone tissue. The composition may be packaged or put into a container, thereby making the composition ready for immediate application to a bone defect site employing any suitable means, e.g., a syringe, spatula, etc (col. 4, lines 33-37).

Alternatively, the bone powder composition can be prepared well in advance and stored under sterile conditions until required for use, e.g., in the barrel of a syringe or other suitable applicator device (col. 4, lines 42-44). In preparing the composition, the bone is first pulverized and then subject to defatting/disinfecting and acid demineralization treatment (col. 2, lines 14-43). As one of ordinary skill in the art would readily appreciate and recognize, these treatments result in any cells present in the bone tissue being lysed.

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. In one embodiment, the human tissue grafting is performed using the patient's own tissue as donor material. Furthermore, the removed tissue can be processed (for example by centrifuging) keeping the components such as bone, cells, and blood and discarding fluid. Therefore, the harvested tissue may be implanted in the donor's own body for grafting (col. 3, lines 57-60).

Applicant respectfully disagrees with the assertion that since O'Leary mentions the use of autogenic bone, it teaches using autogenic bone in the O'Leary composition. First, O'Leary only states two sources of bone powder for his composition: allogenic or xenogenic bone powder. In stating that allogenic bone tissue is preferred, O'Leary is preferring allogenic bone to xenogenic bone. The fact that O'Leary identifies autogenic bone in the background section without specifying that autogenic bone can be used for his bone powder composition actually indicates that O'Leary teaches against using autogenic bone.

Kambin does nothing to remedy the deficiencies of O'Leary. Applicant incorporates herein the previous arguments against the O'Leary/Kambin combination and further notes the following. Even if Kambin could be used to remove bone tissue instead of the soft tissue disc material for which it was intended, Kambin, like O'Leary, is silent about re-implanted the removed material into the same patient. In fact, Kambin is absolutely silent about any reuse of the removed tissue.

Claim 53 now recites a surgical procedure to be conducted on a patient. The surgical procedure comprises the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a

Applicant(s): Peter Bonutti
Application No.: 10/003,996
Examiner: M. Hoffman

location outside of the patient's body, inserting a second tubular member into the patient's body, and moving at least a portion of the body tissue through the second tubular member to a second location in the patient's body. A substance is added to the body tissue after moving the body tissue from the first location through the first tubular member to a location outside of the patient's body and prior to moving the body tissue through the second tubular member. The added substance is a bone growth promoter; and the at least a portion of the body tissue includes cells. As O'Leary and Kambin, either alone or in combination, do not teach or suggest the invention as set forth in claim 53, Applicant respectfully submits that claim 53 is patentably distinct over O'Leary and Kambin. Claims 54 and 55, which depend from claim 53, are submitted to be patentable over the references at least based on their dependencies.

With respect to claim 52, which was rejected based on the combination of O'Leary, Kambin, Muller-Lierheim, and Amrani, Muller-Lierhem and Amrani do nothing to remedy the deficiencies of O'Leary and Kambin. For example, Muller-Lierheim, limited to an implant having a surface coating of growth factors, does not teach or suggest re-implanting at least a portion of body tissue containing cells into the same patient from which the body tissue was taken. Similarly, Amrani is limited to a process for separation and isolation of AHF and fibronectin from blood plasma (which by definition has no cells). As a result, claim 52, which depends from claim 53, is submitted to be patentable at least based on its dependency.

Allowed Claims

Applicant acknowledges with appreciation the allowance of claims 36-44, 46, 47, 49, 51, 57-60, and 69-76. Although claims 51 and 57-60 should have technically be indicated as allowable since they depend from rejected claim 53, Applicant respectfully submits that the amendment to claim 53 should not change the allowability of these claims. Furthermore, claim 57 has been amended to be in independent form and this amendment should not change the allowability of this claim.

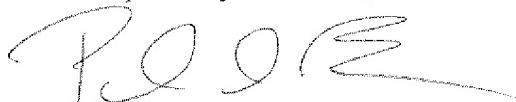
Applicant(s): Peter Bonutti
Application No.: 10/003,996
Examiner: M. Hoffman

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early action is respectfully requested. If any questions remain regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Fees for an RCE and for a two month extension of time are believed to be due and are being submitted via credit card. However, please charge any other required fees (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket no. 780-A02-014-8).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
Paul D. Bianco
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@focusonip.com